EXH A

ORIGINAL

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

JOSHUA KAUFFMAN **1794 Mariners CV** **Loveland, OH 45140**	:	**CASE NO.** A 1 5 0 3 6 6 8 **JUDGE**
Plaintiff,	:	**COMPLAINT AND JURY DEMAND**
v.	:	
ABUBAKAR ATIQ DURRANI, M.D. **PAKISTAN** **(Serve via Hague Convention)**	:	
And	:	(ALL NEW DR. DURRANI CASES SHALL GO TO JUDGE RUEHLMAN PER HIS ORDER)
CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC. **(Serve via Hague Convention)**	:	
And	:	
CHILDREN'S HOSPITAL MEDICAL CENTER **3333 BURNET AVENUE** **CINCINNATI, OH 45229**	:	
Serve: Frank C. Woodsie III **1900 Chemed Center** **Cincinnati, OH 45202** **(Serve via Certified mail)**	:	**REGULAR MAIL WAIVER**
Defendants.	:	

FILED
2015 JUL -9 A 10:53
TRACY WINKLER
CLERK OF COURTS
HAMILTON COUNTY, OH

Now comes Plaintiff, Joshua Kauffman, and files this Complaint and jury demand, stating as follows:

D111203911 INI

PARTIES AND JURISDICTION

1. At all times relevant, Plaintiff Joshua Kauffman, ("Plaintiff", or "Mr. Kauffman") was a resident of and domiciled in the State of Ohio.
2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani ("Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
3. At all times relevant, Center for Advanced Spine Technologies, Inc. ("CAST") was licensed to and did in fact perform medical services in the state of Ohio, and was and is a corporation authorized to transact business in the state of Ohio.
4. At all times relevant herein, Children's Hospital Medical Center ("Children's Hospital") was authorized to transact business and perform medical services in the state of Ohio.
5. At all times relevant herein, Children's Hospital held itself out to the public, and specifically to Plaintiff, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.
6. The medical records reasonably available to Plaintiff's Counsel have been reviewed by a qualified medical expert pursuant to the requirements of Ohio Civ. R. 10(D)(2)(a). An affidavit of Merit is attached to this Complaint.
7. The amount in controversy exceeds the jurisdictional threshold of this Court.
8. The subject matter of the Complaint arises out of medical treatment by the Defendants in Hamilton County, Ohio. This Court is thus the proper venue to grant the Plaintiff the relief he seeks.
9. This case has been previously 41(A) voluntarily dismissed and now is being re-filed.

FACTUAL ALLEGATIONS OF PLAINTIFF

10. In or around spring 2007, Joshua Kauffman began experiencing severe lower back pain while trying out for a baseball team.

11. Sometime between February 19 and April 3, 2007, Joshua was referred by his primary care physician, Dr. Daniel Walters to Cincinnati Children's Hospital Division of Pediatric Orthopedic Surgery for evaluation.

12. The Orthopedist Diane Von Stein MD, stated Plaintiff had kyphotic deformity with pain above and below the area of the fixed kyphosis involving his upper back.

13. On or about February 19, 2007, Mr. Kauffman had x-rays for scoliosis taken at Children's Hospital.

14. The x-rays showed that Mr. Kauffman had exaggerated kyphosis moderately severe centered at the lower thoracic column, which as consistent with Scheuermann Disease Mild.

15. Dr. Von Stein stated that, "I do not see any evidence of spondylolisthesis and there is no evidence of scoliosis as well."

16. Dr. Von Stein recommended a posterior spinal fusion with correction to include spinal osteotomies in the middle.

17. Joshua Kauffman went to Dr. Durrani for a second opinion.

18. Joshua Kaufmann was referred to Dr. Durrani at Children's Hospital by a friend of Joshua's mother.

19. Dr. Durrani acknowledged the kyphosis in Joshua's lower back with the apex of the deformity at T10-11 disk.

20. The x-ray performed at this visit dated July 10, 2007, according to Dr. Durrani, shows

a standing deformity measuring L2 to L4-5 to be approximately 75 degrees and on the hyperextension view, his deformity comes down to 25 degrees. It was noted that Joshua was a Risser III as seen on previous x-rays; yet the images for this date have never been produced. (See exhibit A)

21. During the first visit, Dr. Durrani recommended surgery.
22. On or about July 10, 2007, Dr. Durrani explained to Joshua Kauffman that it would take the brain approximately 6 weeks to several months to compensate for the corrected kyphosis and to balance his neck on his spine.
23. Dr. Durrani informed Joshua that the protrusion of his neck will be significant at first post-operatively but this will go away gradually.
24. Information was conveyed to Joshua's mother and grandmother that after aquatic and land therapy Joshua would be able to return to full sports activity, baseball in 6 months but should take care with contact sports.
25. Dr. Durrani never mentioned the use of Infuse/rhBMP-2 by name in as well as no mention of educational materials given at this time only verbal communication along with a tour of the facility.
26. Dr. Durrani did not offer Mr. Kauffman any conservative treatment options.
27. On August 24, 2007, when Mr. Kauffman was 15 years old, Dr. Durrani performed surgery on Mr. Kauffman at Children's Hospital.
28. Upon information and belief, the informed consent signed by Mr. Kauffman's mother prior to surgery, Dr. Durrani was going to perform a Thoracic 2 to L3 posterior fusion with instrumentation and auto/allo bone graft, Ponte osteotomies, and spinal monitoring.

29. The post-operative report by Dr. Durrani indicated that he performed a Thoracic 3 to L3 posterior fusion and instrumentation, and T9, T10, and T11 posterior Ponte osteotomy. (See Exhibit B)

30. Additionally, the September 11, 2007 scribed note in the presence of Dr. Durrani, this was Joshua's first post operation visit, states that patient had Scheuermann's Kyphosis, 2 weeks status post posterior spinal fusion and instrumentation from T4 to L3, showing just another inconsistency in the reporting. (See exhibit E)

31. Dr. Durrani used Infuse/BMP-2 in Mr. Kauffman's surgery without Mr. Kauffman's knowledge or consent, causing Mr. Kauffman harm. (See exhibit B)

32. There was hardware failure during the surgery, it was indicated in the operative report that after the insertion of the pedicle screws all the screws were stimulated for their impedance, however the impedance for the right sided L2 and T12 screws were found to be unacceptable and there was a medial breach found on the L2 level.

33. The L2 screw was then redirected more laterally.

34. Upon information and belief, immediately following surgery, Mr. Kauffman experienced extreme pain.

35. Joshua's pain was so severe that he could not even put a sock on without being in extreme nerve pain.

36. Dr. Durrani told Mr. Kauffman that the pain had something to do with his nerves, but that he did not know the cause of the pain.

37. Due to Joshua's pain after surgery a CT L-spine without contrast was done at Cincinnati Children's Hospital post-operatively to see if there was a complication with any of the hardware.

38. The CT scan showed in the Lumbar spine, bone graft material was present at multiple levels. (See exhibit C)

39. Following surgery, Mr. Kauffman followed up with Dr. Durrani at Children's Hospital.

40. On September 11, 2007, Joshua attended his first pre-op visit with Dr. Durrani.

41. At this first visit, Dr. Durrani indicates that Joshua was doing well and that Dr. Durrani advised Joshua to wean off the walker and start aquatic therapy on September 12, 2007 3-4 days per week for 6 weeks followed by 6 weeks of land therapy; this was dictated by Dr. Durrani. (See Exhibit D)

42. The same office visit on the same day was dictated by Dr. Viral V. Jain; Dr. Jain's notes state that Joshua was able to walk without support of the walker and without any pain today, and that aquatic therapy was to start tomorrow for 6 weeks followed by strength, endurance, and range of motion therapy, which is not what Dr. Durrani's report stated. (See Exhibit E)

43. Dr. Jain's report states that Joshua had just started walking with the walker and Dr. Durrani's report states that Joshua needs to be weaning off the walker.

44. On that same September 11, 2007 visit the Outpatient Clinic Progress Sheet indicated that Joshua had pain in his back even though Dr. Durrani and Dr. Jian said he did not. (See exhibit F)

45. Dr. Durrani recommended that Mr. Kauffman attend physical therapy to help with his pain.

46. The physical therapy did not help Mr. Kauffman's pain.

47. Mr. Kauffman continued to follow up with Dr. Durrani at CAST after Dr. Durrani left

Children's Hospital.

48. Mr. Kauffman continued to experience pain in his lower back and a loss of flexibility.

49. Dr. Durrani told Mr. Kauffman that this type of pain was normal.

50. Dr. Durrani gave Mr. Kauffman muscle relaxers to help the pain, but they did not relieve Mr. Kauffman's pain.

51. Mr. Kauffman now experiences constant pain in his lower back and left leg.

52. On a daily basis, if Mr. Kauffman sits or stands for prolonged periods his pain is a 6 out of 10 on the pain scale.

53. Additionally, Mr. Kauffman experiences pain in his right scapular area if he lies on it for a long period of time.

54. Mr. Kauffman is now unable to participate in any contact sport.

55. Plaintiff before the surgery lifted weights frequently, he loved it, now he can no longer deadlift at all.

56. Plaintiff can not engage in any exercise that puts weight on his back.

57. Joshua Kauffman, missed his entire freshman year of high school due to his surgery with Dr. Durrani and when he returned to school he only went part-time because he could not sit through school the entire day.

58. Mr. Kauffman has visited several orthopedic surgeons, all of whom have told Mr. Kauffman that the best they can do is recommend more physical therapy to help reduce his pain.

59. Mr. Kauffman has been prescribed muscle massages, physical therapy, steroid injections, and a TENS unit to treat his pain, all to no avail.

60. Upon information and belief, the surgery performed by Dr. Durrani was medically

unnecessary and/or improperly performed.

61. As a direct and proximate result of Mr. Kauffman's surgery, Dr. Durrani's negligence, and Defendant's negligence, Mr. Kauffman has suffered harm.

62. Mr. Kauffman did not become aware of Dr. Durrani's use of Infuse/BMP-2 until he contacted his undersigned counsel.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

63. This information is to demonstrate the overall negligence and inappropriate actions of Dr. Durrani and the hospitals he worked with and/or for and/or in an individual capacity.

64. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

65. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

66. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

67. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

68. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

69. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

70. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

71. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

72. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

73. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

74. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

75. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

76. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

77. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

78. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

79. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

80. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

81. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

82. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

83. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

84. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

85. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.

86. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.

87. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.

88. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.

89. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.

90. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

91. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.

92. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

93. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

94. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

91. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ

Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

92. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

93. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly

contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

94. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically,

the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

95. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

96. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

97. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

98. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

99. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

100. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

101. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

102. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

103. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

104. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

105. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

106. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

107. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

108. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

a. Recombinant – Artificially created in a lab;

b. Morphogenetic – Evolutionary development of an organism;

c. Protein – Essential for growth and repair of tissue.

109. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

110. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

111. BMP-2 has been shown to stimulate the production of bone.

112. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

113. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

114. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic

product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service ActSec.351(i)1."Available http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

115. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

116. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

117. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

118. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

119. The second part of the bone graft is an absorbable collagen sponge.

120. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

121. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

122. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

123. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

124. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

125. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

126. Infuse should never be used in the vicinity of a resected or extant tumor.

127. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

128. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development;

allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

129. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[1]

130. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[2]

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[1] *Fender v. Medtronic,* 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

[2] *Fender v. Medtronic,* 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

131. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

132. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

133. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

d. Skeletally mature patient, AND

e. At levels L2-S1, AND

f. Confirmed degenerative disc disease (DDD), AND

g. Using only an open anterior or anterior laparoscopic approach, AND[3]

h. Six months of non-operative treatment prior to treatment with the device, AND

i. In combination with the metallic LT-CAGE.[4]

[3] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

See Medtronic Package Insert, "INDICATIONS."

134. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

A. Male Sterility

B. Cancer

C. Increased progression of cancer

D. Suffocation of the cervical region

E. Bone fracture

F. Bowel/bladder problems

G. Loss of spinal mobility or function

H. Change in mental status

I. Damage to blood vessels and cardiovascular system compromise

J. Excessive bone mass blocking the ability to treat pain

K. Damage to internal organs and connective tissue

L. Death

M. Respiratory problems

N. Disassembly and migration of components

O. Dural tears

P. Ectopic and exuberant bone formation

Q. Fetal development complications (birth defects)

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[4] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

R. Foreign body (allergic) reaction

S. Gastrointestinal complications

T. Incisional complications

U. Infection

V. Insufflation complications

W. Neurological system compromise

X. Non-union

Y. Delayed union

Z. Mal-union

AA. Change in curvature of spine

BB. Retrograde ejaculation

CC. Scars

DD. Tissue and nerve damage

EE. Itching

FF. Pain

GG. Hematoma

HH. Anaphylactic reaction

II. Elevated erythrocyte sedimentation rate

135. Injury Percentages:

j. Ectopic Bone Growth-63%

k. Inflammatory Neuritis-15%

l. Osteolysis/Subsidence-13%

m. Acute Swelling-7%

n. Retrograde Ejaculation-2%

o. 85% of time, BMP-2 implanted in off-label use

136. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at Children's Hospital by Dr. Durrani.

137. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

138. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

139. Infuse can be implanted in an off-label manner in three ways:

p. Approach/position: Any approach other than an anterior approach;

q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

r. Discs: Use on multiple levels or on a level outside of L2-S1.

140. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

141. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA ... [a]

PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

142. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

143. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

144. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

145. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

146. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

147. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

148. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

149. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

150. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

151. Medtronic anticipated that both products would initially be limited in application.

152. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

153. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been

approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

154. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

155. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

156. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

157. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine,* which followed industry standards before printing peer-reviewed material. See article in the journal *Spine,* published in 2000.

158. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

159. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"

b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

160. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

161. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated

Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization…fixation procedures are as important as the biochemical composition of the 'filler.'"

162. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

163. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

164. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

165. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

166. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

167. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

168. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

169. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

170. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant

sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

171. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

172. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

173. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

174. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

175. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

176. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

177. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft…"

178. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

179. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical

analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

180. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

181. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "...may become the new gold standard in spinal fusion surgery."

182. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

183. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

184. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

185. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has

reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

186. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

187. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

188. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

189. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

190. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

191. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

192. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

193. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

t. That they need to seek medical attention immediately at the first sign of an airway complication

u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury

194. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

195. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

196. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

197. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

198. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

199. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

200. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

201. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

202. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

203. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

204. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

205. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

206. Major findings of the investigation include:

a. Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who

received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

207. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine,* the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

208. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

209. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

210. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

211. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

212. In total, the YODA study analyzed the data from 1,409 participants.

213. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

214. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed

journal publications reported a comprehensive list of all adverse events that occurred during the studies.

215. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

216. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

217. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

218. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

219. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

220. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

221. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

222. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

223. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

224. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

225. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and

benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

226. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

227. BMP-2 is not supposed to be used in minors.

228. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

229. BMP-2 should not be used with women in child bearing years.

230. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

231. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

232. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

233. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

234. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."

235. Dr. Durrani was a paid consultant for Medtronic.

236. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

237. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

238. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

239. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

240. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

241. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

242. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

243. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

244. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

245. Medtronic's website has no information regarding their relationship with Dr. Durrani.

246. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

247. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

248. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

249. Again, this information is not available on the Medtronic website.

250. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

251. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

252. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

253. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the

renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

254. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

255. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

256. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

257. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

258. David Rattigan, was Dr. Durrani's main Medtronic representative from Bahler Medical.

259. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition was taken June 5, 2015.

260. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

261. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

244. The purpose of the background information on the following Defendants and BMP-2 concerning other hospitals is to show the egregious methods, which upon information and belief were used at all hospitals.

245. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

246. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

247. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

248. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

249. **Informed Consent for Surgical or Medical Procedure and Sedation:**

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

250. The Defendants had the responsibility to carry out these consent rules.

251. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

252. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

253. Dr. Durrani is a consultant for Medtronic.

254. Defendants did not inform Plaintiffs of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

255. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

256. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

257. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

258. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

259. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

260. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a

patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

261. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

262. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiffs their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

263. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

264. Defendants did not inform Plaintiffs that Dr. Durrani used Infuse/BMP-2 in his surgeries.

265. Plaintiffs would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

266. Plaintiffs would not have consented to the use of BMP-2 Plaintiff's body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

267. The written informed consent of Dr. Durrani signed by Plaintiffs lacked the disclosure of Infuse/BMP-2's use in his procedures.

268. Plaintiffs never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

269. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

270. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

271. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

272. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

273. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

INFUSE/BMP-2

274. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

275. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

276. Dr. Durrani is a consultant for Medtronic.

277. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

278. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

279. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

280. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

281. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

282. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

283. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

284. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

285. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

286. Dr. Durrani used BMP-2 in Plaintiff in manners not approved by Medtronic or the FDA.

287. Defendant's did not inform plaintiff that Dr. Durrani used Infuse/BMP-2 in his surgery.

288. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

289. Plaintiff would not have consented to the use of BMP-2 in his body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

290. The written informed consent of Dr. Durrani and Children's Hospital signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in his procedure.

291. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

292. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

293. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

294. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

295. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

296. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

297. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

298. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgeries, and improper follow-up care addressing a patient's concerns.

299. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the prayer for relief.

COUNT II: BATTERY

300. Dr. Durrani committed battery against Plaintiff by performing surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

301. Plaintiff would not have agreed to the surgery if he knew the surgery was unnecessary, not approved by the FDA, and not indicated.

302. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the prayer for relief.

COUNT III: LACK OF INFORMED CONSENT

303. The informed consent forms from Dr. Durrani and Children's Hospital which they required Plaintiff to sign, failed to fully cover all the information necessary and required for the procedure and surgical procedure performed by Dr. Durrani. Dr. Durrani and Children's Hospital each required an informed consent release.

304. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before the Plaintiff's surgery.

305. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with his surgery and procedure

306. Had Plaintiff been appropriately informed of the need or lack of need for the surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedure.

307. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

308. Dr. Durrani's conduct as described above was intentional and reckless.

309. It is outrageous and offends against the generally accepted standards of morality.

310. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.

311. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

312. Dr. Durrani made material, false representations to Plaintiff and his insurance company related to Plaintiff's treatment including: stating the surgery was necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgeries would be simple or was "no big deal", that Plaintiff would be walking normally within days after surgery, that the procedure was medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

313. Dr. Durrani also concealed the potential use of Infuse/BMP-2 in Plaintiff's surgery, as well as concealed other information, when he had a duty to disclose to Plaintiff his planned use of the same.

314. These misrepresentations and/or concealments were material to Plaintiff because they directly induced the Plaintiff to undergo his surgery.

315. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

316. Dr. Durrani made the misrepresentations before, during, and after the surgery, with the intent of misleading Plaintiff and his insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery, and to induce Plaintiff to undergo the surgery without regard to medical necessity and only for the purpose of receiving payment.

317. The misrepresentations and/or concealments were made during the Plaintiff's office visits with Dr. Durrani at Children's Hospital and/or CAST.

318. Plaintiff was justified in his reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

319. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo the surgery, which were paid for in whole or in part by his insurance company, and suffered all damages requested in the prayer for relief.

COUNT VI: SPOLIATION OF EVIDENCE

320. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, emails, paperwork, and related evidence.

321. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

322. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

323. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

324. Dr. Durrani is in fact, the owner of CAST.

325. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.

326. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

327. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

328. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT HIRING, RETENTION, & SUPERVISION

329. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

330. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

331. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.

332. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

333. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

334. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the prayer for relief.

COUNT III: FRAUD

335. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that CAST falsely represented that Plaintiffs surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

336. These bills constituted affirmative representations by CAST that the charges related to Plaintiff's surgery were medically appropriate and properly documented.

336. The bills were sent by CAST to Plaintiff insurance falsely represented that Plaintiff's surgery was appropriately indicated, performed and medical necessary in contra-indication of the standard of care.

337. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for CAST's services in association with Dr. Durrani's surgery.

338. As a direct and proximate result of this reliance on the billing of CAST, Plaintiff incurred medical bills that he otherwise would not have incurred.

335. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

336. CAST intentionally concealed and/or misrepresented material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgery and procedures Dr. Durrani performed on Plaintiff at Children's Hospital.

337. Plaintiff was unaware that Infuse/BMP-2 would be used in Plaintiff's surgery and therefore, was unaware of the health risks of Infuse/BMP-2 use in Plaintiff's spine.

338. Had Plaintiff known before Plaintiff's surgery that Infuse/BMP-2 would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at Children's Hospital.

339. Plaintiffs are still awaiting billing from CAST reflecting the exact totals charged for the use of BMP-2 on the client.

340. As a direct and proximate result of the fraud against Plaintiff by CAST, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

341. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

342. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

343. CAST omitted suppressed and concealed from Plaintiff facts with the intent that Plaintiff rely on these omissions, suppressions and concealments as set forth herein.

344. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

345. CAST was fully aware of its actions.

346. CAST was fully aware that Plaintiff was induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiff.

347. Had Plaintiff been aware that CAST's representations as set forth above were untrue, Plaintiff would not have used the services of Defendants.

348. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

349. CAST's actions were not the result of any bona fide errors.

350. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiff has suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring CAST restore to Plaintiff all money received from Plaintiff plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiff;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

iv. Such other and further relief that this Court deems just and appropriate.

COUNT V: SPOLIATION OF EVIDENCE

351. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, emails, paperwork and related evidence.

352. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

353. CAST's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

CHILDREN'S HOSPITAL COUNTS:

COUNT I: VICARIOUS LIABILITY

354. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of Children's Hospital through December 2008.

355. Defendant Dr. Durrani was performing within the scope of his employment with Children's Hospital during the care and treatment of Plaintiff.

356. Defendant Children's Hospital is responsible for harm caused by acts of its employee's for conduct that was within the scope of employment under the theory of respondeat superior.

357. Defendant Children's Hospital is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

358. As a direct and proximate result of Defendant Children's Hospital's acts and omissions, Plaintiff sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, & RETENTION

359. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute medical negligence, lack of informed consent, battery, and fraud.

360. Children's Hospital negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician by:

a. Violating their JCAHO rules by allowing Dr. Durrani to repeatedly violate the Children's Hospital bylaws with it's full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied and reapplied for privileges at Children's Hospital;

c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by Children's Hospital staff, doctors, Dr. Durrani's patients and by others;

d. Ignoring information they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including West Chester/UC Health, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

361. The Safe Medical Device Act required entities such as Children's Hospital to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

362. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiff sustained all damages requested in the prayer for relief.

COUNT III: FRAUD

363. Upon information and belief, Plaintiff believes the bills request by Plaintiff will indicate that Children's Hospital falsely represented that Plaintiffs surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

364. The bills sent by Children's Hospital to Plaintiff's insurance falsely represented that Plaintiff's surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

365. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for Children's Hospital's services in association with Dr. Durrani's surgery.

366. As a direct and proximate result of this reliance on the billing of Children's Hospital Plaintiff incurred medical bills that he otherwise would not have incurred.

367. Children's Hospital also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 would be used in Plaintiff's surgery, or

misrepresented to Plaintiff the nature of the surgery and the particular risks that were involved therein.

368. Children's Hospital's concealments and misrepresentations regarding Infuse/BMP-2 and the nature and risks of Plaintiff's surgery were material facts.

369. Because of its superior position and professional role as a medical service provider, Children's Hospital had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

370. Children's Hospital intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgery and procedures Dr. Durrani performed on Plaintiff at Children's Hospital.

371. Plaintiff was unaware that Infuse/BMP-2 would be used in Plaintiff's surgery and therefore, was unaware of the health risks of Infuse/BMP-2 use in Plaintiff's spine.

372. Had Plaintiff known before Plaintiff's surgery that BMP-2/Infuse would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at Children's Hospital.

373. Plaintiff is still awaiting billing from Children's Hospital reflecting the exact totals charged for the use of BMP-2 on the Plaintiff.

374. As a direct and proximate result of the fraud upon Plaintiff by Children's Hospital Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

375. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

376. Children's Hospital's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

377. Children's Hospital omitted suppressed and concealed from Plaintiff facts with the intent that Plaintiff rely on these omissions, suppressions and concealments as set forth herein.

378. Children's Hospital's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

379. Children's Hospital was fully aware of its actions.

380. Children's Hospital was fully aware that Plaintiff was induced by and relied upon Children's Hospital's representations at the time Children's Hospital was engaged by Plaintiff.

381. Had Plaintiff been aware that Children's Hospital's representations as set forth above were untrue, Plaintiff would not have used the services of Defendants.

382. Children's Hospital, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

383. Children's Hospital's actions were not the result of any bona fide errors.

384. As a result of Children's Hospital's unfair, deceptive and unconscionable acts and practices, Plaintiff has suffered and continues to suffer damages, which include, but are not limited to the following:

d. Loss of money paid

e. Severe aggravation and inconveniences

f. Under O.R.C. 1345.01 Plaintiff is entitled to:

i. An order requiring Children's Hospital restore to Plaintiff all money received from Plaintiff plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiff;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

iv. Such other and further relief that this Court deems just and appropriate.

COUNT V: PRODUCTS LIABILITY

385. At all times Infuse/BMP-2 is and was a product as defined in R.C. § 2307.71(A)(12) and applicable law.

386. Children's Hospital (aka supplier) supplied either Medtronic's (aka manufacturer) Infuse/BMP-2 for surgery performed by Dr. Durrani on Plaintiff.

387. Children's Hospital, as a supplier, failed to maintain Infuse/BMP-2 properly.

388. Children's Hospital did not adequately supply all components required to use either Infuse/BMP-2 properly.

389. Children's Hospital knew or should have known the FDA requirements and Medtronic's requirements for using either Infuse/BMP-2.

390. Children's Hospital stored either Infuse/BMP-2 at its facility.

391. Children's Hospital ordered either Infuse/BMP-2 for surgery performed by Durrani.

392. Children's Hospital did not adequately warn Plaintiff that Infuse/BMP-2 would be used without all FDA and manufacturer required components.

393. Children's Hospital did not gain informed consent from Plaintiff for the use of Infuse/BMP-2, let alone warn of the supplying of the product without FDA and manufacturer requirements.

394. Children's Hospital failed to supply either Infuse/BMP-2 (aka product) in the manner in which it was represented.

395. Children's Hospital failed to provide any warning or instruction in regard to Infuse/BMP-2, and failed to make sure any other party gave such warning or instruction.

396. Plaintiff suffered physical, financial, and emotional harm due to Children's Hospital's violation of the Ohio Products Liability act.

397. Plaintiff's injuries were a foreseeable risk.

398. Plaintiff did not alter, modify or change the product, nor did Plaintiff know that the product was being implanted without all required components.

399. Children's Hospital knew or should have known that the product was extremely dangerous and should have exercised care to provide a warning that the product was being used and that the product was being used outside FDA and manufacturer

requirements. The harm caused to Plaintiff by not providing an adequate warning was foreseeable.

400. Children's Hospital knew that the product did not conform to the representation of the intended use by the manufacturer yet permitted the product to be implanted into Plaintiff.

401. Children's Hospital, as a supplier, acted in an unconscionable manner in failing to supply the product without all FDA and manufacturer required components.

402. Children's Hospital, as a supplier, acted in an unconscionable manner in failing to warn Plaintiff that the product was being supplied without all FDA and manufacturer required components.

403. Children's Hospital's actions demonstrate they took advantage of the Plaintiff's inability, due to ignorance of the product, to understand the product being implanted without FDA and manufacturer required components.

404. Children's Hospital substantially benefited financially by the use of the product as the product allowed for Defendant to charge more for the surgery.

405. Plaintiff suffered economic loss as defined in R.C. § 2303.71(A)(2) and applicable law.

406. Plaintiff suffered mental and physical harm due to Children's Hospital's acts and omissions.

407. Plaintiff suffered emotional distress due to acts and omissions of Children's Hospital and is entitled to recovery as defined in R.C, § 2307.71(A)(7) and applicable law.

408. Children's Hospital violated the Ohio Products Liability Act R.C. § 2307.71-2307.80.

409. Children's Hospital violated R.C. § 2307.71(A)(6).

410. Children's Hospital violated The Ohio Consumer Sales Practices Act R.C. § 1345.02-.03.

411. Children's Hospital provided inadequate warnings are defined in R.C, § 2307.76(A) and applicable law.

COUNT VI: SPOLIATION OF EVIDENCE

412. Children's Hospital through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, emails, paperwork and related evidence.

413. Children's Hospital through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

414. Children's Hospital's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;

4. Lost future income and benefits;

5. Loss of ability to earn income;

6. Past pain and suffering;

7. Future pain and suffering;

8. Plaintiff seeks a finding that his injuries are catastrophic under Ohio Rev. Code §2315.18;

9. All damages permitted under Ohio Products Liability Act R.C. §2307.71-2307.80, and all other applicable law;

10. All incidental costs and expenses incurred as a result of his injuries;

11. The damages to his credit as a result of his injuries;

12. Punitive damages;

13. Costs;

14. Attorneys' fees;

15. Interest;

16. All property loss;

17. All other relief to which he is entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

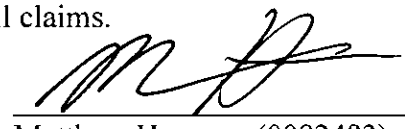
Respectfully Submitted,

Matthew Hammer (0092483)
Lindsay Boese (0091307)
Attorneys for Plaintiff
5247 Madison Pike
Independence, KY 41051

Phone: 513-729-1999
Fax: 513-381-4084
mhammer@ericdeters.com

JURY DEMAND

Plaintiff makes a demand for a jury under all claims.



Matthew Hammer (0092483)
Lindsay Boese (0091307)

Cincinnati Children's

EXHIBIT A

Division of Pediatric Orthopaedic Surgery

Eric J. Wall, MD
Director

Aaron W. Perlman, MD
Emeritus

Alvin H. Crawford, MD
Charles T. Mehlman, DO, MPH
Twee T. Do, MD
Junichi Tamai, MD
Diane Von Stein, MD
Atiq Durrani, MD
Associates

Lance Bolin
Angela Kramig
Physician Assistant

Sandy Singleton
Business Director

07/10/2007

Daniel Walters, M.D.
8859 Brookside Drive
West Chester, OH 45069

RE: KAUFFMAN, JOSHUA
DOB: 03/22/1992
MRN#: 841613
ACCT#: 163903669
DATE OF SERVICE: 07/10/07
DX:

Dear Dr. Walters,

HISTORY: We have seen above-named patient who is a 15-year-old male patient who carries the diagnosis of Scheuermann kyphosis. He has kyphosis in his lower thoracic spine with the apex of the deformity at T10-11 disk. He has complaints of occasional back pain in his lower thoracic spine as well. He is here for his preop visit. He is scheduled to undergo surgery on August 24, 2007. He is otherwise fine. There is no change in his complaints in the interval in that he was seen first today.

PHYSICAL EXAMINATION: Physical examination shows him to be a well-built, somewhat overweight male individual. He has significant kyphosis of his lower thoracic spine, which is fairly flexible on extension view. A neurological examination was performed on today's visit, which shows him to be neurologically intact. He on today's visit did not complain of any pain.

LABORATORY DATA/X-RAYS: The x-rays were taken today, which included the standing lateral view as well as the hyperextension over a bolster view. The standing view shows that his deformity when measured from L2 to T4-5 is approximately 75 degrees. On hyperextension view, his deformity is fairly flexible and comes down to 25 degrees. He is a Risser III as seen on previous x-ray.

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MEDICAL DECISION MAKING: A number of questions were asked on today's visit, and the explanation was also done in a detailed fashion. We have explained to the family that we are aiming for the higher normal range of the kyphosis. As far as the correction is concerned, that would be around 40 degrees. This will allow his locomotion system as well as the brain to compensate for the corrected kyphosis and to balance his neck on his spine. However, we have cautioned the family that initially for approximately 6 weeks to several months until the brain adapts to the new position of his spine, he will have protrusion of his neck, which will be fairly significant when seen clinically. However, we expect this to gradually go away. We also explained to the family that patients with kyphosis are at high risk for developing neurological complication as compared to the scoliosis, and we are going to perform the correction in a very gradual fashion with full spinal cord monitoring. As far as the rehabilitation following the surgeries concerned, he will have sufficient mobility of his lumbar spine to allow him to play sports. However, we would prefer him to start sports activity approximately 6 months after the surgery. As far as the contact sports are concerned, we do not want to restrict him in any way; however, we would prefer that he avoids contact sports, particularly football. His main interest as far as a sport is concerned is in baseball, and we have said that he will be able to do that 6 months following the surgery. The rehab protocol will involve physical therapy in terms of aquatic therapy after 2 weeks of the surgery, which will gradually convert to the land therapy, and he can go back to full sports activity after 6 months.

As far as postop health is concerned, he will more than likely not require IC unless there is significant problem doing the surgery. He will not require any brace after the surgery. The incision will be a single midline long incision, which will be closed by subcuticular sutures. Therefore, he will have only 1 scar.

The long-term complication that is likely to occur in his case is the adjacent segment degeneration in the lumbar spine. We will explain this in full detail with the family as this usually occurs because of the long movement term of the fused spine. This complication may or may not occur in his case; however, we have explained to him that this spine surgery may not be his last spine surgery. At this point, we think that patient as well as the family understand all the risks, complications, and benefits of the procedure and are in consent for undergoing the surgery.

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Dr. Durrani was present in the consultation, discussion, and examination of this patient. Thank you again for referring this patient to us and allowing us to participate in the management of your patient.

Signed: A. Atiq Durrani, M.D.
08/16/2007 11:29 EDT

Sincerely,

A. A Durrani, M.D.
DICTATED BY: Viral V Jain, M.D.

__X__I was present the entire visit/procedure, and I agree with the PA-C/ Resident/Fellow's documentation above.

D: 07/10/2007 10:06:15 Voice#24735167
T: 07/10/2007 13:35:46 Doc#19641898
AAD/dts482503

Cincinnati Children's Hospital Medical Center
MLC 2017, 3333 Burnet Avenue, Cincinnati, OH 45229-3039 .
Appointments 513-636-4454 ♦Referral Fax Line 513-636-4487 ♦ Administrative Office 513-636-4785, Fax 513-636-3928
www.cincinnatichildrens.org

Cincinnati Children's

Patient KAUFFMAN, JOSHUA DARREN MR # 841613
Pt # 500277300

Adm Date
Rm/Bed

Post Operative Note | Aug 26, 2007 16:40

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

OPERATIVE REPORT

PATIENT NAME: KAUFFMAN, JOSHUA
BIRTH DATE: 03/22/1992
MRN #: 841613
BILLING #: 164660300
FLOOR: A1
DATE OF PROCEDURE: 08/24/07

EXHIBIT B tabbies

PREOPERATIVE DIAGNOSIS: Scheuermann's kyphosis.

POSTOPERATIVE DIAGNOSIS: Scheuermann's kyphosis.

PROCEDURES PERFORMED:
1. T3 to L3 posterior spinal fusion and instrumentation.
2. T9, T10 and T11 posterior Ponte osteotomy.

PERFORMING SURGEON: A. Atiq Durrani, M.D.

ASSISTANT(S): Viral V. Jain, M.D.

INSTRUMENTATION: We used Medtronic Legacy titanium instrumentation system with 6.35-mm rods. We put polyaxial pedicle screws at levels T3, T4, T6, T8, T12, and L1 bilaterally. We used polyaxial Ponte reduction screws at levels L2 and L3 bilaterally. The screws were connected with each other by 6.35-mm titanium rods. The screws in the T12 to L3 were 6.5 mm in diameter, while the screws in the rest of the thoracic spine were 5.5 mm in diameter.

OSTEOBIOLOGICS: We used Helios bone morphogenic protein and Vitoss synthetic bone graft material.

COMPLICATIONS: There was a transient decrease in the motor potentials of L5 level during the performance of the Ponte osteotomy on the left side, which recovered within 2 minutes.

INDICATIONS: This is a 15-year-old male who presented to us with the complaints of back pain, along with the kyphotic deformity. The preoperative x-rays showed that the patient had Scheuermann's kyphosis with the apex of the kyphosis located in the region of T11 vertebra. This was responsible for the extensive period of back pain that he has. The surgery was recommended for this excision of the deformity, as well as for the pain relief.

After understanding all the risks and the benefits of the procedures, the patient, as well as the family, have consented for the procedure.

PROCEDURE: The patient was brought in the operating room, was identified and was given preoperative antibiotics. He was given general endotracheal anesthesia. The electrodes were placed for spinal cord monitoring for monitoring of both motor, as well as the sensory, functions. The patient was then placed prone on the Jackson table on 4 posts to aid in the reduction of the kyphosis. His back was then prepped and draped in the usual sterile fashion. The baseline potentials were popped in for spinal cord monitoring.

A longitudinal midline incision was placed starting from T3 all the way to L3. The subcutaneous tissues were dissected out and the spinous processes of the vertebrae were exposed. The level identification was performed with fluoroscopy. After that, the entire spine from T3 to L3 was exposed in standard fashion from one transverse process to another. Care was taken not to damage the facet joints and intraspinous ligament at T2-3 and L3-4 levels.

Under the guidance of the anatomic landmarks, which were the confluence of pars, the transverse process and the lower end of the superior articular process for the lumbar spine, and the confluence of the superior half of the transverse process and the base of the lateral half of the superior articular process, the entry hole was made for the pedicle screw insertion. The pedicle screw were further introduced in the standard fashion at the instrumented levels above. During the insertion of the pedicle screws with the help of high speed burr, the inferior facet of the vertebra above were removed and the cartilage was also burred out in order to perform the facet joint fusion. Care was taken not to damage the facet joints of L2-3 and L1-2 joints.

PONTE OSTEOTOMIES: With the help of the high speed burr the lower half of the lamina of the T11 vertebra was cleaned out and removed with the help of the large rongeur. The ligamentum flavum was also then removed with the help of the Kerrison rongeur. With the help of the Woodson and cottonoid patties, the dura was separated from the overlying ligament and the remaining portion of the lamina of T11 and the superior articular process of the T12 vertebrae were removed. This procedure was then repeated on the opposite side as well. This was a clear space was obtained between the T12 pedicle and the inferior articular process of T11 vertebrae.

A similar procedure was repeated at the levels of T10 and T9. During the performance of the Ponte osteotomy at T9 vertebra, there was a transient

decline in the motor potentials on the left side for L5 segments. These motor potentials returned to the baseline within 2 minutes. At this stage, the _____ was everted to infuse 500 mg of Solu-Medrol.

The appropriate size rod was then cut and bent in appropriate kyphosis and lordosis. The left sided rod was then placed first, starting from the thoracic level, gradually introducing the rod in the pedicle screws and going towards the lumbar spine. The Ponte reduction screws greatly helped in the insertion of the rod. Once the rod was reduced in its proper position, a significant correction of the deformity was achieved. The right sided rod was similarly introduced and further correction of the deformity was achieved. After that, a compression was applied across the apex of the deformity in the region of the Ponte osteotomies. This resulted in the closure of the osteotomies posteriorly. At this stage excellent correction of the deformity was achieved. The position of the screws, as well as the instrumentation, were checked under fluoroscopy, and was found satisfactory.

With the help of the high speed burr, the dorsal cortices of the laminae and the spinous processes of the vertebrae were decorticated. With the help of osteotome, the fish scaling was performed for the laminae of the thoracic, as well as the lumbar, vertebrae as far as possible. The exposed dura was then covered with the help of large Gelfoam and several strips of Helios were placed on the fusion mass. Several strips of Infuse bone morphogenic protein were then placed along the fusion bed. Vitoss synthetic bone graft was then applied over the fusion mass. The patient's autologous bone obtained from the facetectomies, as well as from the Ponte osteotomies, was also applied over the fusion bed.

Throughout the course of the procedure, frequent irrigation with antibiotic mixed saline solution was performed, and at the end of the procedure.

After insertion of the pedicle screws, all the screws were stimulated for their impedance. The impedance for the right sided L2 and T12 screws was found unacceptable. Therefore, these screws were checked. There was a medial breach found on the L2 level. Therefore, this screw was then redirected more laterally. There was no pedicle breach found at the T12 level. Therefore, this screw was re-inserted. The rest of the screws had acceptable impedance levels.

The closure of the wound bed was then performed with 1-0 Vicryl, taking interrupted sutures for the paraspinous muscles and fascia. A subcutaneous Hemovac drain was placed, and the subcutaneous tissues were closed with 2-0 Vicryl, taking interrupted sutures. The skin was closed with 4-0 Monocryl, taking subcuticular sutures. Steri-Strips and a sterile dressing were then applied.

Cincinnati Children's

Patient KAUFFMAN, JOSHUA DARREN MR # 841613
Pt # 500277300

Adm Date
Rm/Bed

The patient tolerated the procedure well. He was then shifted to the regular bed in supine position, and was extubated. The patient was then transferred to post-anesthesia care unit in stable condition.

Dr. Durrani was the primary surgeon, and was present and scrubbed throughout the case.

A. Atiq Durrani, M.D.

Dictated by: Viral V. Jain, M.D.

D: 08/26/2007 16:40:52 Job #25624622
T: 08/27/2007 12:55:20 Doc #20346203
AAD/dts482521

Signed: A. Atiq Durrani, M.D. 08/28/2007 07:53

Page created: Friday, August 1, 2008 9:36 AM For: PARPU8

Protocol Information

END OF REPORT

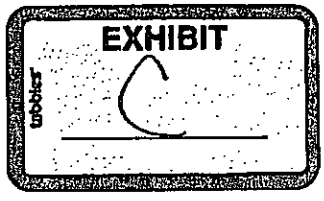
Result Information

Status	Provider Status
Final result (8/24/2007 6:58 PM)	Ordered

CT L-SPINE WO CONTRAST [2553318] Resulted: 08/24/07 1858, Result Status: Final result

Resulted by:	Jones, Blaise V.	Performed:	08/24/07 1858 - 08/24/07 1858
Resulting Lab:	CCM RADIOLOGY	Specimen:	08/24/07 1858
Narrative:	*** Final Report ***		

Clinical History: 15-year-old with kyphosis status post spinal fusion. L5 dysphasia. Complains of left leg pain. Evaluate for hardware complication.



Comparison: None.

Technique: Helical images were obtained in 1 mm sections from the lower cervical spine through the sacrum. Coronal and sagittal reconstructions were created after imaging was obtained.

Findings:

Thoracic spine:

Patient is a recent postoperative state. Scoliosis rods and pedicle screws are present from the T3 through L3 level. There is evidence of postsurgical change with subcutaneous emphysema, a subcutaneous drain, as well as small locules of air within the spinal canal. The right-sided T3 pedicle screw appears to enter the spinal canal before it continues into the vertebral body. The left-sided pedicle screw at this level extends beyond the vertebral body and exits with its tip just into adjacent to the aortic arch. The right-sided pedicle screw at T4 extends slightly into the spinal canal. The pedicle screws at T6 pas through the pedicles bilaterally. A hole for a right-sided pedicle screw at the T7 level is present. The right-sided pedicle screw at T8 extends lateral to the pedicle. The left-sided pedicle screw at this level is likely completely contained by the pedicle however may extend laterally. Evaluation of the soft tissue is limited due to extensive beam hardening artifact from the surgical hardware. The visible lungs are clear.

Protocol Information (continued)

CT L-SPINE WO CONTRAST [2553318] (continued) Resulted: 08/24/07 1858, Result Status: Final result

Lumbar spine:

Evidence of postsurgical changes are present in the lumbar spine with subcutaneous emphysema as well as locules of air within the spinal canal. Pedicle screws are present at T12, L1, L2, and L3. The right-sided pedicle screw at L2 extends into a portion of the spinal canal with its tip is within the vertebral body. The remainder pedicle screws extend through the pedicle. Bone graft material is present at multiple levels. The spinal canal is significantly narrowed at the L4 and L5 levels due to congenitally short pedicles. Evaluation of the soft tissue is limited due to beam hardening artifact from the surgical hardware.

Impression: Thoracic spine

1. Postsurgical changes as described.

2. Multiple pedicle screws extending partially into the central canal as described.

3. Left-sided T3 pedicle screw extending beyond the vertebral body and ending with its tip adjacent to the aortic arch.

Lumbar spine:

1. Postsurgical changes as described.

2. Right-sided L2 pedicle screw extending partially into the central canal.

3. Narrowing of the central canal due to congenitally short pedicles at the L4-L5 level.

ADDITIONAL FINDINGS AFTER ATTENDING RADIOLOGIST REVIEW: I CONCUR WITH THE ABOVE REPORT WITH THE EXCEPTION OF THESE ADDITIONAL FINDINGS / COMMENTS:

1. In the preliminary report, the term "central canal" was used to described the spinal canal. That has been edited.

2. Breech of the medial margin of the pedicles by transpedicular screws

Protocol Information (continued)

CT L-SPINE WO CONTRAST [2553318] (continued) Resulted: 08/24/07 1858, Result Status: Final result

at multiple levels described above is felt to be relatively minor, without significant compromise of the spinal canal.

3. In addition to the congenital stenosis described above, the facet articulations at L4-L5 are abnormal, with some fragmentation and abnormal orientation of the superior and inferior articulating facets. These findings appear to be a chronic abnormality, but associated symptoms may be increased by the recent surgery.

Interpreted By: ALEXANDER TOWBIN

**Verified By:

BLAISE JONES, M.D. on 08/25/2007 07:38

via Electronic Signature**

The attending radiologist has reviewed the images and agrees with this report.

Testing Performed By

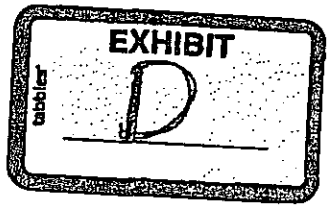
Lab - Abbreviation	Name	Director	Address	Valid Date Range
13 - Unknown	CCM RADIOLOGY	Unknown	Unknown	08/16/07 1515 - Present

Order **CT L-SPINE WO CONTRAST [CT 0000] (Order 2553318)**

CT L-SPINE WO CONTRAST [2553319] Standing

Ordering User:	Edi, Results Encounter Match 08/24/07 1756	Authorized by:	Greiwe, Raymond M., MD
Frequency:	ONCE 08/24/07 1858 - 1 Occurrences		
Electronically signed by:	Edi, Results Encounter Match 08/24/07 1756		

Cincinnati Children's



Division of Pediatric Orthopaedic Surgery

Eric J. Wall, MD
Director

Aaron W. Perlman, MD
Emeritus

Alvin H. Crawford, MD
Charles T. Mehlman, DO, MPH
Twee T. Do, MD
Junichi Tamai, MD
Diane Von Stein, MD
Atiq Durrani, MD
Associates

Lance Bolin, PA-C
Angela Kramig, PA-C
Physician Assistant

Sandy Singleton
Business Director

09/11/2007

RE: KAUFFMAN, JOSHUA
DOB: 03/22/1992
MRN#: 841613
ACCT#: 165198052
DATE OF SERVICE: 09/11/07

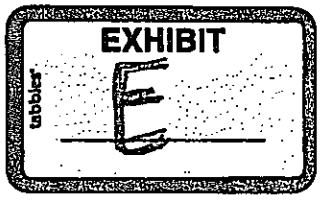
Josh is here today for repeat evaluation and is doing very well. The wound looks absolutely fine. However, his hypersensitivity is almost gone. He is now 6 feet tall today, which is about a 3-inch increment from his pre-operative height. He is doing very well, and I told him to start weaning off the walker now. He is going to start aquatic therapy as of tomorrow, and he is going to do 3-4 days per week of this therapy. He will do aquatic therapy for the next 6 weeks, and after 6 weeks he will start doing land therapy. I will see Josh back in 3 months.

Signed: A. Atiq Durrani, M.D.
09/18/2007 10:47 EDT

A. A Durrani, M.D.

D: 09/11/2007 11:26:21 Voice#25930600
T: 09/12/2007 08:51:00 Doc#20580799
AAD/dts482551

Cincinnati Children's



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Physician Assistant

Sandy Singleton
Business Director

09/11/2007

RE: KAUFFMAN, JOSHUA
DOB: 03/22/1992
MRN#: 841613
ACCT#: 165198052
DATE OF SERVICE: 09/11/07
DX: Scheuermann's kyphosis, 2 weeks status post posterior spinal fusion and instrumentation from T4 to L3

I scribed this note in the presence of Dr. Atiq Durrani.

HISTORY: We have seen the above-named patient who is a 15-year-old male who comes for follow up of his back surgery. He is doing fine as far as his postoperative period is concerned. He has started mobilizing and is walking with the walker support. He currently has some back pain; however, it is not very troublesome at this moment.

PHYSICAL EXAMINATION: Physical examination reveals that his wound is well healed. It is clean and the dressing is clean and dry. On today's visit, he was able to walk without any pain and without any support. He does not have any neurologic complaints or any neurologic signs, as well.

MEDICAL DECISION MAKING: We feel that the patient is doing fine. We would like him to start physical therapy, the first 6 weeks of which would be aquatic therapy. After that, he will start therapy for strength, endurance, and range of motion. We would like to see him back in a period of 3 months, at which time we will take posterior and lateral standing x-rays of his spine.

Thank you again for referring this patient to us and allowing us to participate in the management of your patient.

__X__ I was present the entire visit/procedure, and I agree with the Resident/Fellow's documentation above.

Signed: A. Atiq Durrani, M.D.
09/18/2007 10:47 EDT

A. A Durrani, M.D.

Dictated By: Viral V. Jain, M.D.

D: 09/11/2007 12:27:00 Voice#25913432 T: 09/11/2007 14:55:35 Doc#20569867 AAD/dts481214

Cincinnati Children's Hospital Medical Center
MLC 2017, 3333 Burnet Avenue, Cincinnati, OH 45229-3039 .
Appointments 513-636-4454 ♦Referral Fax Line 513-636-4487 ♦ Administrative Office 513-636-4785, Fax 513-636-3928
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EXHIBIT F

Cincinnati Children's Hospital Medical Center

OUTPATIENT CLINIC PROGRESS SHEET

841613 R ORR 15Y 5 M
KAUFFMAN, JOSHUA DARREN
165198052 ORR 03/22/1992
K90 M DURRANI, A. ATI
09/11/07 513-860-0446

Clinic: Ortho Date: 9/11/07
Last Visit: Post op Visit Accompanied By: Mom & Gra
Primary Care Physician: Dr Wallace Referred By: West Chester

REASON FOR VISIT: fu Scheuermann's Kyphosis
S/p T3 to L3 PSF 6/9/10
T11 Posterior Ponte Osteotomy
DOS: 8/24/07
Wound √ only

WT ___ kg WT ___ % 162LBS / 6FT
☐ HT ☐ Length ___ cm HT ___ % HC ___ cm
O_2 SAT ___ T ___ °C ☐ Oral ☐ Rectal ☐ Axillary ___
☐ Electronic HR ___ RR ___
☐ Manual BP ___

CUFF	POSITION	LOCATION	ACTIVITY
☐ Neonate ☐ Adult	☐ Sit	☐ R Arm	☐ Quiet
☐ Infant ☐ Small	☐ Stand	☐ L Arm	☐ Cry
☐ Child ☐ Medium	☐ Supine	☐ ___	☐ ___
☐ Thigh ☐ Large	☐ Held	☐ ___	

Signature/Credentials ___

DEVELOPMENT: ☒ Age Appropriate

DELAYS:	FUNCTION:	THERAPIES:
☐ Motor	☐ Independent	☐ PT ___ ☐ OT ___
☐ Cognitive	☐ Assisted	☐ Speech ___
☐ Speech	☐ Dependent	☐ Early Intervention ___
☐ Other	☐ Other	☐ Other ___

Signature / Credentials ___

PSYCHOLOGICAL:
☐ Cooperative ☐ Uncooperative
☐ Interactive ☐ Quiet
☐ Smiling ☐ Anxious
☐ Playing ☐ Fussy
☐ Emotional Concerns ☐ Sleeping ☐ Alert

SOCIAL:
☐ Home with ___
☐ Daycare ___
☒ School / Work 1st grade
☐ Attendance ☐ Home School
☐ Individual Education Plan (IEP)
☐ Activities ___
☐ Financial Issues
☐ Transportation Issues
☐ Tobacco use / exposure

CULTURAL / SPIRITUAL:
☐ None Related To Care

NUTRITION SCREENING
☐ Yes* ☒ No ☐ IV Nutrition ☐ Special Formula ☐ Tube Feeding ☐ NG ☐ G-Tube ☐ J-Tube
☐ Yes* ☒ No ☐ Weight Changes ☐ Concerns ☐ Related To Feeding ☐ Appetite ☐ Allergies
If Yes*, ☐ Health Care Provider notified of nutrition concern
☐ Current Management ___
☐ Directed To ___
☐ Refer to Nutrition Clinic ☐ Sub specialty RD

PAIN: ☒ Yes ☐ No
Site ___
Onset Back

PAIN TYPE (✓)	DURATION (✓)
☒ Current	☐ Constant
☐ Chronic	☐ Intermittent
☐ Intermittent	☐ Other
☐ Procedural	

QUALITY (✓)	SCALES / SCORES (✓)
☐ Sharp	☐ NIPS ___
☐ Throbbing	☐ CHEOPS ___
☒ Aching	☐ OUCHER ___
☐ Dull	☒ VAS 4
☐ Burning	☐ Unable to score:
☐ Spasm	☐ Neurological
☐ Other	☐ Developmental
☐ Unable to describe	☐ Behavioral

COMMENTS: ___

INTERVENTION ("Also Complete All Education Sections Below")

Intervention	Education	
☐	☐	Home Management Discussed
☒	☐	Medications
☐	☐	Continue Current Treatment Plan ___
☐	☐	Distraction
☐	☐	Non Pharmacological ___
☐	☐	Child Life
☐	☐	Relaxation Techniques

☐ Directed To ___
☐ Referred To ___
Signature / Credentials

REASSESSMENT
☐ Situationally Inappropriate
☐ Unable to assess
☐ Score ___

EDUCATION ☐ None Indicated ☒ Yes ☐ Per Patient

READINESS TO LEARN	BARRIERS TO LEARNING	METHOD (Preferred / Actual)	SUBJECT
Learner # 1: Mom	#1 / #2		☐ Pain Management
Learner # 2: Patient	☐ ☐ None	☐ ☐ Verbal	☐ Diagnosis
#1 / #2	☐ ☐ Distraction	☐ ☐ Demo	☐ Treatment Time to give pt Wallace
☐ ☐ Attentive	☐ ☐ Cognitive	☐ ☐ Written	☐ Medication Stm PT appointment Therapy
☐ ☐ Denies need	☐ ☐ Physical	☐ ☐ Audio/Visual	☐ Equipment
☐ ☐ Uncooperative	☐ ☐ Emotional	☐ ☐ Health Topic	☐ Surgery / Procedure for 3-4x week for 6 wks
☐ ☐ Other	☐ ☐ Cultural / Spiritual	☐ ☐ Visual Aid	☐ Radiology
	☐ ☐ Language	☐ ☐ Other	☐ Home Care Home based Therapy 6 wks
	☐ ☐ Other		☐ Other RTC: 3 MO.

EVALUATION: ☐ Return Demonstration ☒ Verbalizes Understanding ☐ Reinforcement Needed ☒ Instructed To Call With Questions

COMMENTS: ___

Signature / Credentials

ORDERS: Take 6 wks to stop having sensitivity in shoulder blade

Provider Signature / Credentials

K 1000 HIC 07/06 — ORIGINAL - CCHMC MEDICAL RECORD — YELLOW - CLINIC FILE — SG Form No. 100032 07/06

OUTPATIENT CLINIC PROGRESS SHEET

JOSH KAUFFMAN'S AFFIDAVIT OF MERIT FOR CHILDREN'S

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.

2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.

3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.

4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges.

5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.

6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.

7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for Cincinnati Children's Hospital.

8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Josh Kauffman and the medical treatment of Josh Kauffman at Children's.

9. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.

10. I have also reviewed the nursing summary prepared by legal counsel's office for Josh Kauffman. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific

information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

11. Based upon my review, the following are the facts I rely upon:

A. Joshua Kauffman is now a 22 year old Caucasian male, currently a full time college student. His past medical history includes back and left leg pain and at times frequent urination.

B. In early spring 2007, Josh Kauffman began experiencing severe, lower back pain while attending tryouts for a baseball team. He saw Dr. Robert Hill, orthopedic surgeon at Ohio Valley, who referred him to a chiropractor. On 2/19/07 Joshua completed scoliosis xrays at CCHMC, which showed exaggerated kyphosis moderately severe centered at lower thoracic column consistent with Scheuermann Disease. Mild associated 8 degrees lower thoracic scoliosis convex to the right. His mother then made an appointment with Dr. Durrani, after being referred to him by a friend.

C. Joshua's first and only surgery was medically unnecessary. No conservative treatments were offered or trialed prior to surgery.

D. Dr. Durrani misinterpret a pre-operative diagnostic on Post-op CT results.

E. Dr. Durrani recommended surgery at the first visit (07/10/07).

F. Dr. Durrani performed one surgery on the patient.

G. DATE: 08/24/07 SURGERY (CCHMC): PROCEDURES: The Informed Consent obtained read "Thoracic two – lumbar three posterior fusion with instrumentation and auto/allo bone graft and ponte osteotomies, spinal monitoring", signed by Joshua's mother, Angela Kauffman. The Operative Report by Dr. Durrani indicate the following procedures were completed: Thoracic 3 to L3 posterior spinal fusion and instrumentation, and T9, T10 and T11 posterior Ponte osteotomy.

H. Information from Dr. Durrani's OR report indicates that rhBMP-2 was used during Joshua surgery.

I. The following hardware was implanted:

The Operative Record-Implant log indicated the following were used:
6 Titanium multi axial screws 5.5 X 35
6 Titanium multi axial screws 6.5 X 40
6.35mm Hexended lined rods
12 break off screw set, titanium
16 ml Infuse* Bone Graft (rhBMP-2/ACS)
2 VITOSS Scaffold
2 Medtronic Legacy titanium instrumentation system

J. According to the PMA submitted by Medtronic to the FDA, Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components that the Infuse device consists of are 1.) A metallic spinal fusion cage (the LT-Cage), 2.) The bone graft substitute, which consists of liquid rhBMP-2, and 3.) A spongy carrier or scaffold for the protein that resides in the fusion cage. With the exception of two non-spinal uses not relevant here, the FDA has not approved any other use of Infuse, including the insertion of rhBMP2 into Mr. Kauffmann's skeletally immature thoracic and lumbar spine and unapproved hardware combinations by Dr. Durrani. The use of rhBMP-2 without the expressed or written consent and/or knowledge of Joshua or his parents, Charles and Angela Kauffman is a violation of standards of care, as well as a violation of the manner in which rhBMP2 could be used, in accordance with the FDA. Additionally, Medtronic states in its booklet that Infuse is contraindicated for children under the age of 21, as they are skeletally immature. CCHMC failed to properly supervise Dr. Durrani and the CCHMC OR staff, and this failure caused harm to Joshua and his parents.

K. This report was dictated two days later by Dr. Viral V. Jain on 8/26/2007 and signed by Dr. Abubakar Durrani on 8/28/07.

L. There was failed hardware. It was indicated on the Operative Report after insertion of the pedicle screws, all the screws were stimulated for their impedance. The impedance for the right sided L2 and T12 screws were found unacceptable. There was a medial breach found on the L2 level. Therefore the screw was then redirected more laterally. Also during the performance of the Ponte osteotomy at T9 vertebra there was a transient decline in the motor potentials on the left side for L5 segments which returned to baseline within 2 minutes.

M. Client states, "After completing all of the physical therapy Dr. Durrani prescribed, I have still suffered with chronic upper and lower back pain. I have followed up with him several times within the past five years, and he simply stated that the pain was normal for this type of procedure. Prior to the surgery, he never indicated that this would be something I would have to live with. He did state that I would never be able to play full contacts sports again because of the rods. Since the surgery, I have visited numerous chiropractors and orthopedic doctors to try to treat the pain. All of the treatments only temporarily relieve the pain. The pain never goes completely away. I've been prescribed muscle massage, physical therapy, a TENS unit, all to no avail. I haven't seen any doctors to try to determine whether or not something wrong happened during surgery. Up until recently, I just accepted Dr. Durrani's explanation that this pain is normal."

N. His lower back and left leg pain is a constant deterrent and reminder not to engage in activities that cause an increase in pain. On a daily basis if he sits or stands for prolonged periods of time his pain is 6/10 scale. He also experiences pain 5/10 in his right scapular area if he lies on it for a long period of time. Recently he tried running and after a short distance he felt like he had been hit with a bat in his lower back preventing him from continuing. Joshua stated it took an hour rest for the pain to diminish to where it was

tolerable. His leg pain is intermittent but the lower back pain is constant and limits his activities.

O. Joshua and family are following up with an orthopedist and cardiac surgeon at the time of this writing regarding possible screw migration from the aortic arch. Client and family were told by Dr. Durrani that all post-op CT results had come back normal back in 2007.

12. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani and Cincinnati Children's Hospital which proximately caused harm to Plaintiff:

A. Unnecessary surgery(s). Number of surgeries 1, Number unnecessary 1

B. Need to have additional surgery to repair problems created by Dr. Durrani

C. Implantation of BMP-2 without informed consent

D. Failed hardware

E. Failure to obtain proper informed consent for surgery

F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education

G. Failure to properly post-op monitor the patient

H. Failure to properly perform follow up, post-op care

I. Negligent surgical techniques

J. Failure to maintain accurate and complete surgical records and surgical consent forms

K. Failure to disclose important health information to patient

L. Failure to maintain and complete discharge summary

M. Failure to supervise Dr. Durrani

N. Negligent pre-surgical diagnosis

O. Failure to prepare a timely operative report or other medical record

P. Billing for services not completed

Q. Not informing the patient another surgeon will be doing all or part of the surgery

R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications

S. Deviation in standard of care

T. Failure to perform thorough and accurate pre-op nonsurgical evaluation

U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason

V. Failure by CAST to disclose additional/changed procedure and reason to patient

W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis

X. Prior knowledge of possible complication and not acting properly upon same

Y. Failure to disclose pertinent health information to another health care provider

Z. Fraudulent, negligent and reckless pre-operative work up

AA. Fraudulent, negligent and reckless surgery

BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses

CC. Failure to properly educate patient regarding diagnoses

DD. Failure to attempt non-surgical conservative treatment

EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation

FF. Failure by Dr. Durrani at CCH to perform accurate and complete preoperative teaching

GG. Failure by Dr. Durrani at CCH to properly educate patient regarding diagnoses

HH. Failure by Dr. Durrani at CCH to maintain accurate and/or complete medical records

II. Failure of informed consent by Dr. Durrani at CCH

JJ. Failure of CCH to insure Dr. Durrani and CAST had obtained proper informed consent

KK. Failure of CCH to obtain proper acknowledgement of consent

LL. Failure by Dr. Durrani at CCH to disclose pertinent health information

MM. Failure by CCH to disclose additional/changed procedure and reason to patient

NN. Failure by CCH to supervise staff

OO. Failure by CCH staff to properly document abnormalities and follow up care

PP. Non-approved hardware combinations

QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Josh Kauffman and concealed material facts he had a duty to disclose. CCH and CAST concealed material facts they had a duty to disclose. Josh Kauffman was justified in relying on the misrepresentation and did rely proximately causing harm to Josh Kauffman. Dr. Durrani and CCH intentionally misled Josh Kauffman. Josh Kauffman had the right to correct information.

13. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to CCH pertaining to the claims against them. CCH's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. CCH are both being referenced when only CCH is named. I hold the following opinions relative to CCH pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani joined Children's Hospital until he left by January 1, 2009. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

1. CCH's motive for their actions and inactions towards Dr. Durrani was financial gain.

2. The MEC, administration and Boards of CCH failed to "govern the affairs of the Medical Staff."

3. The MEC, administration and Boards of CCH failed to enforce their rules upon Dr. Durrani as they were required to do.

4. The MEC, administration and Boards of CCH failed to provide oversight of Dr. Durrani as they were required to do.

5. The MEC, administration and Boards of CCH failed to properly evaluate Dr. Durrani.

6. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.

7. The MEC, administration and Boards of CCH failed to properly discipline Dr. Durrani including summary suspensions and revocation.

8. The MEC, administration and Boards of CCH failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.

9. The MEC, administration and Boards of CCH ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.

10. The MEC, administration and Boards of CCH failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.

11. The MEC, administration and Boards of CCH certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.

12. The MEC, administration and Boards of CCH failed to act on Dr. Durrani's failure in medical record documentation.

13. The MEC, administration and Boards of CCH failed to require Dr. Durrani to follow the rules for off label experimental procedures.

14. The MEC, administration and Boards of CCH allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including fellows and interns.

15. The MEC, administration and Boards of CCH allowed Dr. Durrani to do multiple surgeries at once.

16. CCH have refused to provide as privileged the peer review information from CCH for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.

17. Based upon all of the above, it's my opinion that CCH were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at CCH under the standards of Ohio and this proximately caused harm to Plaintiff.

18. The facts support Josh Kauffman's claim for negligence, battery, lack of consent and fraud.

19. As a result of the negligence and conduct of Dr. Durrani and CCH Josh Kauffman suffered damages proximately caused by them, including the following:

A. Permanent disability
B. Physical deformity and scars
C. Past, Current and Future Physical and Mental Pain and Suffering
D. Lost income past, present and future
E. Loss of enjoyment of life
F. Past medical expenses
G. Future medical expenses approximately in the amount of $_____
H. Aggravation of a pre-existing condition
I. Decreased ability to earn income
J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT

KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by Keith D. Wilkey, M.D. on this 23 day of ~~April~~ June, 2014.

Angela Kay Poinsett
NOTARY PUBLIC
My Commission Exp.: 07/18/2015
St. Louis County
State of Missouri

ANGELA POINSETT
Notary Public - Notary Seal
State of Missouri
Commissioned for St. Charles County
My Commission Expires: July 18, 2015
Commission Number: 11133613

COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

REQUEST AND INSTRUCTIONS FOR ORDINARY MAIL SERVICE

Joshua Kauffman
Plaintiff

-vs-

Children's Hospital Medical Center
Defendant

INSTRUCTIONS TO THE CLERK

CASE NUMBER: A 1503668

IF SERVICE OF PROCESS BY CERTIFIED MAIL IS RETURNED BY THE POSTAL AUTHORITIES WITH AN ENDORSEMENT OF "REFUSED" OR "UNCLAIMED" AND IF THE CERTIFICATE OF MAILING CAN BE DEEMED COMPLETE NOT LESS THAN FIVE (5) DAYS BEFORE ANY SCHEDULED HEARING, THE UNDERSIGNED WAIVES NOTICE OF THE FAILURE OF SERVICE BY THE CLERK AND REQUESTS ORDINARY MAIL SERVICE IN ACCORDANCE WITH CIVIL RULE 4.6 (C) OR (D) AND CIVIL RULE 4.6 (E).

Matthew J. Hammer
ATTORNEY OF RECORD **(TYPE OR PRINT)**

07/09/2015
DATE

\s\Matthew J. Hammer
ATTORNEY'S SIGNATURE

TRACY WINKLER
CLERK OF COURTS
HAMILTON COUNTY, OH.
2015 JUL -9 A 10:53
FILED

COMMON PLEAS COURT
HAMILTON COUNTY, OHIO

Joshua Kauffman FILED

CASE NO. A 1503668

VS

Abubakar Atiq Durrani, MD, et al.

WRITTEN REQUEST FOR SERVICE
TYPE OF PAPERS TO BE SERVED ARE

Complaint with Affidavit of Merit

( ) **PLEASE CHECK IF THIS IS A DOMESTIC CASE**

PLAINTIFF/DEFENDANT REQUESTS:

CERTIFIED MAIL SERVICE X

PERSONAL SERVICE _____

PROCESS SERVICE _____

EXPRESS MAIL SERVICE _____

REGULAR MAIL SERVICE _____

RESIDENCE SERVICE _____

FOREIGN SHERIFF _____

ON Children's Hospital Medical Center, Serve: Frank C. Woodside, III

1900 Chemed Center, Cincinnati, Ohio 45202

Matthew J. Hammer
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